



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

3 2 4 4 5 AUG 18 P 2 :20

AUG 16 2005

James L. Wilmer, Ph.D.
Director, Scientific Affairs
Market America, Inc.
1302 Pleasant Ridge Road
Greensboro, North Carolina 27409

Dear Dr. Wilmer:

This is in response to your letter of July 11, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that the following statements will made for the following product Advanced Level 90's:

"[M]aintaining healthy, stable blood glucose levels."
"Start on your way to healthy blood sugar levels...."
"Blood Sugar Maintenance."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, claims that do not establish that the claims are about blood glucose levels that are already within normal limits imply that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claims you are making for this product represent that the product is intended to affect blood glucose but do not also include a statement about it being intended to affect blood glucose that is already in the normal range, they are implied disease claims.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this


97S 0162 LET 842

Page 2 - Dr. James L. Wilmer

product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,


for

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Atlanta District Office, Office of Compliance, HFR-SE140

1302 Pleasant Ridge Road
Greensboro, North Carolina 27409
Voice: 336.605.0040



FAX: 336.605.0041
E-Mail: mamerica@morebv.com
Web Site: marketamerica.com

July 11, 2005

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S. W.
Washington, D. C. 20204

JUL 25 2005

Dear Sir/Madam:

I have enclosed notification forms that are intended to comply with Section 6 of the Dietary Supplement Health and Education Act of 1994 and Rule 21 C.F.R. §101.93. One dietary supplement called *Advanced Level 90*[®] is discussed. I have listed the structure-function statements found on the product label and associated support literature, and have identified the product ingredients that are the subject of the statements.

Thank you.

Sincerely,

A handwritten signature in black ink that reads "James L. Wilmer".

James L. Wilmer, Ph. D.
Director, Scientific Affairs

Enclosures: 1 original and 2 copies

2005-4866
Aims

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **1302 Pleasant Ridge Road, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Advanced Level 90®**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: “Advanced Level 90 is a supplement designed from a unique combination of vitamins, trace minerals and herbs that have been proven safe and effective in maintaining healthy, stable blood glucose levels.”—Brochure

Statement 2: “Start on your way to healthy blood sugar levels today with Advanced Level 90 and other support products.”—Brochure

Statement 3: “Blood Sugar Maintenance” —Bottle Label

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
--------------------------------	--

- | | |
|--------------|--|
| 1.-3. | Advanced Level 90® is composed of the following ingredients: biotin, magnesium (oxide), zinc (gluconate), chromium (nicotinate), glucomannan, alpha-lipoic acid, <i>Gymnema sylvestre</i> , American ginseng, vanadium (amino acid chelate); other ingredients include: dicalcium phosphate, microcrystalline cellulose, stearic acid, magnesium stearate, croscarmellose sodium, and silicon dioxide. |
|--------------|--|

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.-2.	Advanced Level 90®	Brochure
3.	Advanced Level 90®	Bottle

I, James L. Wilmer, am authorized to certify this Notification on behalf of Market America, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Market America, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: July 10, 2005

By: James L. Wilmer
James L. Wilmer, Ph. D.
Director, Scientific Affairs
Market America, Inc.